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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H 2058 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/06778	International filing date *(day/month/year)* 26.06.2003	Priority date *(day/month/year)* 27.06.2002
International Patent Classification (IPC) or both national classification and IPC A61F9/01		
Applicant TECHNOVISION GMBH GESELLSCHAFT FÜR ... et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26.01.2004	19.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Rick, K Telephone No. +49 89 2399-7246

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/06778

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-16 received on 06.10.2004 with letter of 06.10.2004

Drawings, Sheets

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☒ the claims, Nos.: 17-36
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The document US-A-5 683 379 as cited by the applicant and considered to represent the most relevant state of the art, discloses an apparatus for laser vision correction, comprising means for controlling the apparatus to deliver a myopia correcting nominal laser ablation in an optical zone identified for myopia correcting nominal ablation of an exposed corneal surface of an eye and further to deliver a laser ablation in a region outside of the identified optical zone.

2. The subject-matter of claim 1 differs from US-A-5 683 379 in that said region outside of the identified optical zone is separated therefrom by a minimum distance.

3. The above feature solves the problem to create a central flattening of the corneal surface in said optical zone via a controlled biodynamic response and thereby to reduce the amount of laser ablation needed inside said optical zone for full myopia correction.
The same argumentation applies to US-A-6 302 877 of the international search report also disclosing an apparatus for laser vision correction to deliver laser ablation in a corneal region outside of an identified optical zone. Furthermore, in contrast to the device of the present invention, US-A-6 302 877 relates to the correction of presbiopia and accordingly a different optical zone ("not used for far distance viewing", see col. 12, l. 66 to col. 13, l. 5) is defined.
All further documents of the international search report are less relevant for the subject-matter of present claim 1. Accordingly the combination of features of claim 1 is neither known, nor rendered obvious by, the available prior art and meets the requirements of Article 33(2)-(4) PCT.

4. Claims 2-16 dependent thereon define further advantageous embodiments and as such also meet the requirements of Article 33 PCT.

What is claimed is:

1. A method for laser vision correction, comprising providing a controlled biodynamic response in corneal tissue of an eye by inflicting a controlled trauma to an exposed corneal surface outside an identified optical zone for a myopia correcting nominal laser ablation of the cornea.

2. The method of claim 1, wherein providing the controlled biodynamic response includes a flattening of the corneal surface over at least a central portion of the optical zone.

3. The method of claim 1, wherein inflicting the controlled trauma comprises laser ablating a portion of the exposed corneal surface.

4. The method of claim 3, wherein laser ablating a portion of the exposed corneal surface comprises ablating at least a portion of a ring of corneal tissue having a circular or an acircular shape.

5. The method of claim 4, wherein the at least a portion of the ablation ring has an inner boundary adjacent an outer boundary of the optical zone.

6. The method of claim 5, wherein the inner boundary of the at least a portion of the ablation ring begins at a distance, d, from the outer boundary of the optical zone, where $200\mu m \leq d \leq 600\mu m$.

7. The method of claim 4, comprising ablating the at least a portion of the ring to a depth, t, where $10\mu m \leq t \leq 70\mu m$, and having a width, w.

8. The method of claim 7, wherein t and w are variable as a function of biodynamic ablation location on the cornea.

9. The method of claim 7, wherein w is a function of the laser beam diameter on the cornea.

10. The method of claim 7, wherein w has a nominal value of about 1mm.

11. The method of claim 4, comprising ablating the at least a portion of the ring within a transition zone of the nominal ablation of the cornea.

12. The method of claim 1, wherein providing the controlled biodynamic response comprises creating a tissue ablation volume for a desired refractive correction that is less than a corresponding tissue ablation volume for the desired refractive correction in the absence of the controlled biodynamic response.

13. The method of claim 12, wherein the lessened tissue ablation volume has a smaller ablation depth over the optical zone than a corresponding ablation depth over the optical zone in the absence of the controlled biodynamic response.

14. The method of claim 1, wherein providing the controlled biodynamic response comprises empirically determining the controlled biodynamic response from a statistically significant population.

15. The method of claim 1, wherein providing the controlled biodynamic response comprises delivering a plurality of photoablative light pulses onto the corneal surface, all of which have only a 1mm diameter.

16. The method of claim 15, wherein the plurality of photoablative light pulses have a direct aperture transmission portion and a diffractive aperture transmission portion so as to produce a soft-spot beam intensity profile.

17. A method for a LASIK or a LASEK myopia correction, comprising:

ablating a volume of corneal tissue outside an optical zone of a nominal ablation region of the cornea.

18. The method of claim 17, wherein the volume of ablated corneal tissue is in the form of at least a portion of a ring of ablated corneal tissue having a circular or an acircular shape.

19. The method of claim 18, wherein the at least a portion of the ring has an inner boundary adjacent an outer boundary of the optical zone.

20. The method of claim 19, wherein the inner boundary of the at least a portion of the ablation ring begins at a distance, d, from the outer boundary of the optical zone, where $200\mu m \leq d \leq 600\mu m$.

21. The method of claim 20, comprising ablating the at least a portion of the ring to a depth, t, where $10\mu m \leq t \leq 70\mu m$, and a width, w.

22. The method of claim 21, wherein t and w are variable as a function of biodynamic ablation location on the cornea.

23. The method of claim 21, wherein w is a function of the laser beam diameter on the cornea.

24. The method of claim 21, wherein w has a nominal value of about 1mm.

25. The method of claim 24, comprising ablating the at least a portion of the ring within a transition zone of the nominal ablation of the cornea.

26. The method of claim 17, wherein ablating the volume of corneal tissue comprises creating a tissue nominal ablation volume in the optical zone for a desired refractive correction that is less than a corresponding tissue nominal

ablation volume in the optical zone for the desired refractive correction in the absence of the controlled biodynamic response.

27. The method of claim 26, wherein the lessened tissue nominal ablation volume has a smaller ablation depth over the optical zone than a corresponding ablation depth over the optical zone in the absence of ablating the volume of corneal tissue.

28. In an improved device readable medium having stored therein an executable instruction for directing an ophthalmic vision correcting laser platform to deliver a myopia correcting nominal ablation in an optical zone of a corneal surface,

the improvement comprising an executable instruction stored in the medium for directing the ophthalmic vision correcting laser platform to deliver a myopia correction enhancing biodynamic ablation in the corneal surface outside of the optical zone.

29. The device readable medium of claim 28, wherein the biodynamic ablation has the form of at least a portion of a ring having an inner boundary adjacent an outer boundary of the optical zone, wherein the ring has a circular or an acircular shape.

30. The device readable medium of claim 29, wherein the inner boundary of the biodynamic ablation is separated from the outer boundary of the optical zone by a distance, d, where $200\mu m \leq d \leq 600\mu m$.

31. The device readable medium of claim 29, wherein the at least a portion of the ring has a depth, t, where $10\mu m \leq t \leq 70\mu m$, and a width, w.

32. The device readable medium of claim 31, wherein t and w are variable as a function of biodynamic ablation location on the cornea.

33. The device readable medium of claim 31, wherein w is a function of the laser beam diameter on the cornea

34. The method of claim 29, wherein w has a nominal value of about 1mm.

35. The device readable medium of claim 29, wherein the at least a portion of the ring is located within a transition zone of the nominal ablation of the cornea.

36. The device readable medium of claim 29, wherein the controlled delivered biodynamic ablation comprises a plurality of photoablative light pulses delivered to the corneal surface, all of which have only a 1mm diameter.